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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,372	11/02/2001	Sojiro Shiokawa	Q64460	8305

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Sughrue Mion Zinn Macpeak & Seas
2100 Pennsylvania Avenue N W Suite 800
Washington, DC 20037-3213

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,372	Applicant(s) SHIOKAWA ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 18-24 are pending in the application.

This action is in response to applicants' amendment dated December 4, 2003.

Claim 1 has been amended, claims 2-17 were canceled and claims 18-24 are newly added.

Response to Amendment

Applicants' arguments filed December 4, 2003 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of the last office action, which are hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-17 over SATO et al., Journal of Medicinal Chemistry of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that claim 1 as amended and newly added claims 18-24 are directed to a compound which has a 5-HT₃ receptor activating action in addition to a 5-HT₃ receptor antagonistic activity. Additionally, the applicant's stated that SATO neither teaches or suggests that a higher 5-HT₃ receptor "antagonistic" activity can be obtained by modifying the substituent on the nitrogen atom of the homopiperazine ring. However,

Art Unit: 1624

6v of SATO teaches a compound that differs only in the presence of a methyl group on the nitrogen atom of the homopiperazine. H vs. Me is not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548 regarding the addition of a Me group to a known compound. Furthermore, applicants should note a replacement of two methyl groups on a known compound with two hydrogen atoms has been held to be *prima facie* obvious due to close structural similarity. Note *In re Hoke*, 195 USPQ 148 and *Ex parte Fauque*, 121 USPQ 425. Thus, one having ordinary skill in the art would have been motivated to prepare the instantly claimed invention because such structurally homologous compounds are expected to possess similar properties.

The 6v compound of SATO is shown to inhibit 5-HT-evoked diarrhea but not inhibit normal bowel function. SATO is only speculative as to the mode of action of 6v, which is **presumably** because of its characteristic 5-HT₃ partial agonist activity. SATO also states that such a compound should be applicable to the treatment of bowel hypersensitivity conditions, such as IBS, without the side effects of constipation. One of ordinary skill in the art would expect that the 5-chloro-2-(1-homopiperazinyl)-7-methylbenzoxazole compound of the instant invention in view of the teachings of SATO to behave in the same fashion as the methylated compound, 6v, which is claimed to have the same utility, i.e. irritable bowel syndrome and diarrhea, without the side effects of constipation.

Claims 1 and newly added claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over SATO et al., *Journal of Medicinal Chemistry*. For reasons of record and stated above.

Art Unit: 1624

4. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-17 over SATO et al., EP 806 419 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that EP '419 discloses benzoxazole compounds having a 5-HT₃ receptor activating action in addition to a 5-HT₃ receptor antagonistic activity, but EP '419 fails to teach or suggest the metabolic stability of the compounds. EP '419 is silent to with respect to the metabolic stability of the compounds. Furthermore, the metabolic stability of the compounds is not a claim limitation.

Claims 1 and newly added claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over SATO et al., EP 0 806 419. For reasons of record and stated above.

In view of the amendment dated December 4, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 23 and 24 are includes

Art Unit: 1624

any and all serotonin 5-HT₃ receptor antagonistic agents and any and all serotonin 5-HT₃ receptor partial activators, which is not described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not stated in the form of a proper Markush grouping.
- b) Claims 18 and 19 are vague and indefinite in that the terminology "a medicament" does not clarify whether the claim is limited to a compound, composition, or even complex composition. Medicament is defined as "an agent that promotes recovery from injury or ailment; a medicine". An agent is defined as "a force or substance that causes a change: a chemical agent". (The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company)
- c) Claim 18 is a substantial duplicate of claim 1, as medicament is defined as an agent, i.e. substance, compound, etc.
- d) Claims 21 and 22 are a substantial duplicate of claim 1, as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.
- e) Claim 21 is a substantial duplicate of claim 1, as agent is defined as a substance, i.e. compound.

Art Unit: 1624

- f) Claim 22 is a substantial duplicate of claim 1, as activator is defined as a substance, i.e. compound, which changes the speed of a chemical reaction.
- g) Claims 23 and 24 are a substantial duplicate of claim 1, as agent is defined as a substance, i.e. compound.
- h) Claims 23 and 24 are vague and indefinite in that it there dependent upon themselves.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,037,342. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and method of use of U.S. '342 embraces the compounds and method of use of the compound of the instant invention.

Art Unit: 1624

8. Claims 1 and 18-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/219,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of copending Application No. 10/219,496 embraces the compound of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

9. Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claims from which they depend in the alternative. See MPEP § 608.01(n).

37 CFR 1.75. Claim(s).

(c) one or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. **Any dependent claim, which refers to more than one other claim (multiple dependent claim) shall refer to such other claims in the alternative only.** A multiple dependent claim shall not serve as a basis for any other multiple dependent claims. For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes, also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application, which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(d). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
February 26, 2004